

Wilzin

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IG/1085/G	<p>This was an application for a group of variations.</p> <p>A.1 - Administrative change - Change in the name and/or address of the MAH</p> <p>A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release</p> <p>A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer</p>	16/05/2019		SmPC, Annex II, Labelling and PL	

¹ Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.

² A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.

³ SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)				
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/03/2019		PL	
IA/0029/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting	14/01/2019	n/a		

	material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/07/2018		Labelling and PL	
PSUSA/3145/201610	Periodic Safety Update EU Single assessment - zinc acetate dihydrate	09/06/2017	n/a		PRAC Recommendation - maintenance
IG/0773/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	14/02/2017	19/02/2018	Annex II and PL	
IA/0025	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	08/12/2016	n/a		

IA/0024	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	25/11/2016	n/a		
IA/0023	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	24/06/2016	n/a		
IG/0686	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/05/2016	n/a		
IA/0021/G	<p>This was an application for a group of variations.</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p> <p>B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)</p>	23/07/2015	n/a		
IA/0020	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	12/06/2015	n/a		

IB/0019	<p>To extend the shelf life of the finished product from 24 to 36 months. The MAH has also taken the opportunity to update the local representatives in the PIL.</p> <p>B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)</p>	18/05/2015	17/05/2016	SmPC and PL	
IAIN/0018/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer</p> <p>B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place</p>	15/04/2015	n/a		
IB/0017	<p>B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition)</p>	10/03/2015	n/a		
IG/0535	<p>C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location</p>	06/03/2015	n/a		

IA/0015/G	<p>This was an application for a group of variations.</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure</p> <p>B.II.c.3.a.1 - Change in source of an excipient or reagent with TSE risk - From TSE risk material to vegetable or synthetic origin - For excipients or reagents NOT used in the manufacture of a biol/immunol AS or in a biol/immunol medicinal product</p> <p>B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer</p> <p>B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer</p> <p>B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)</p>	17/12/2014	n/a		
IG/0393	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	20/12/2013	n/a		
IG/0392	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	19/12/2013	29/01/2014	Annex II and PL	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
IB/0011/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p> <p>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</p> <p>B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place</p>	13/12/2013	n/a		
IA/0012	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	14/11/2013	n/a		
IB/0010	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	17/01/2013	29/01/2014	SmPC and PL	
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/09/2012	29/01/2014	PL	

N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/01/2012	29/01/2014	PL	
IB/0007	B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue	28/07/2010	n/a		
IB/0006	IB_12_a_Change in spec. of active subst./agent used in manuf. of active subst. - tightening IB_12_b_01_Change in spec. of active subst./agent in manuf. of active subst. - test parameter AS IB_25_a_01_Change to comply with Ph. - compliance with EU Ph. - active substance	20/01/2010	n/a		
R/0005	Renewal of the marketing authorisation.	23/07/2009	19/10/2009	SmPC, Annex II, Labelling and PL	Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers that the benefit/risk profile continues to be favourable. The CHMP was also of the opinion that the renewal can be granted with unlimited validity.
IA/0004	IA_01_Change in the name and/or address of the marketing authorisation holder IA_05_Change in the name and/or address of a manufacturer of the finished product	06/09/2007	n/a	SmPC, Annex II, Labelling and PL	
IA/0002	IA_36_b_Change in shape or dimensions of the container/closure - other pharm. forms	06/06/2007	n/a		

IA/0001	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	12/05/2006	n/a		